

REMARKS

Claims 89-128 are currently pending in the present application.

The Restriction Requirement:

In the Office Action, the Examiner has set forth Restriction and Species Election Requirements. The Examiner argues that the application contains claims directed to multiple inventions which lack Unity of Invention, and has required the election of a single invention from among the following FIVE (5) groups:

Group I, claims 89 - 124, drawn to compounds having the formula “[masking group]-[carrier]-[activity moiety],” as recited in claim 89;

Group II, claim 125, drawn to methods of synthesizing a compound with starting materials as defined in formula II or IIb;

Group III, claim 126, drawn to methods of hydrolyzing a polymeric cascade prodrug by placing the prodrug in a solution of pH approximately 7.4;

Group IV, claim 127, drawn to methods of administering an amine-containing moiety via a polymeric cascade prodrug and cleavage thereof; and

Group V, claim 128, drawn to methods of providing a therapeutically useful concentration of biologically active molecule by *in vivo* cleavage of a polymeric cascade prodrug.

The Examiner contends that Groups I, III, IV & V and Group II lack Unity of Invention because “[t]he compounds synthesized by the method of group II are not of the same scope as the compounds of groups I and III-V.” (*See*, the Office Action, p. 4). Additionally, the Examiner contends that Groups I and III-V lack Unity of Invention because the linking technical feature of a polymeric cascade prodrug according to claim 89 is not a special technical feature as it allegedly does not make a contribution over Piccariello, *et al.* (WO 03/057716).

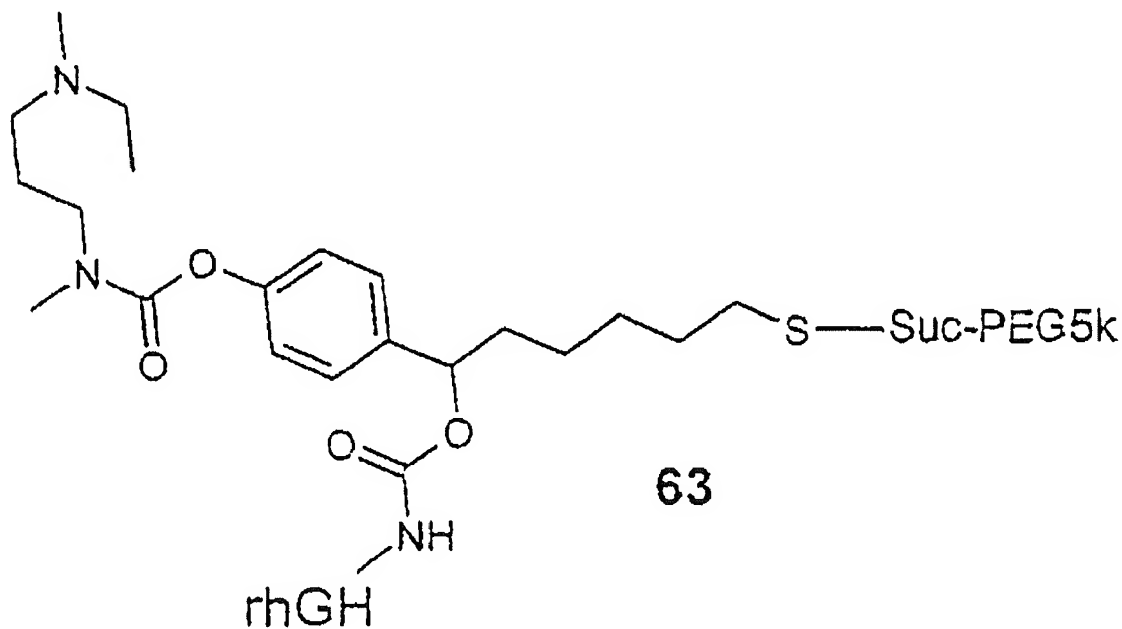
Additionally, in the Office Action, *the Examiner has required the election of a single disclosed species* for initial searching purposes, to which the application will be restricted if no generic claim is allowed. If any one of Groups I, III, IV or V is elected, a specific compound must be elected to serve as an initial search point. If Group II is elected, the

following specific species must be elected: 1) a specific starting molecule of either formula II or IIb; 2) a masking group and the Y2 that masking group is bound to; and 3) the biologically active moiety D.

Provisional Elections with Traverse:

In the event the Examiner is inclined to maintain the Restriction Requirement, despite the traversal remarks which follow, Applicants hereby provisionally elect, *with traverse*, the invention of **Group I**, claims 89-124, for examination on the merits.

In the event the Examiner is inclined to maintain the Species Election Requirement despite the traversal which follows, Applicants hereby provisionally elect, *with traverse*, and solely for initial searching purposes, **Compound 63**, as set forth in the Specification, at page 88, lines 16-18, and as shown below:



Applicants respectfully submit, for the sake of a complete reply, that at least claim 89 is generic to all disclosed species and that claims 89-95, 97-98, 101-102, 110-113, 115-120 and 122-124 read on the elected species.

Traversal:

Applicants respectfully traverse the Restriction Requirement and the Species Election Requirement. The Requirements are improper and unnecessary.

With respect to the alleged lack of Unity between Group II and Groups I, III, IV and V, Applicants submit that compounds prepared by the methods of Group II are within the scope of the compounds of Group I (*i.e.*, claim 89). In other words, while the scope of compounds encompassed by Group I may be broader than the compounds prepared via the methods of Group II, the compounds prepared by the methods of Group II are all encompassed by Group I. The fact that the scope of compounds which can be prepared by the methods of Group II is narrower than the scope of compounds in Group I is not a valid basis for restriction. Reconsideration and withdrawal of the Restriction Requirement in this regard is respectfully requested.

With respect to the alleged lack of Unity between Group I and Groups III, IV and V, Applicants submit that any search of the subject matter of Group I will necessarily encompass the methods of Groups III, IV and V, all of which are dependent from Group I (claim 89). Simultaneous examination of all pending claims does not present an undue burden on the Examiner.

Applicants further submit that the Species Election Requirement is also unnecessary and improper. The mere fact that the application discloses more than one distinct species is not an appropriate basis for insisting upon election of a single disclosed species. The International Search Report and the Examiner's own basis for asserting a lack of Unity of Invention based on WO 03/057716, make it clear that an election of a single disclosed species is unnecessary for searching purposes.

Applicants respectfully request that, if upon maintaining the Species Election Requirement, the Examiner carries out the search for the elected species and finds no suitable prior art upon which to base a rejection for the provisionally elected species, that in accordance with normal Office procedure, the search be broadened to cover other disclosed species as recited in the instant Specification.

Additional Issues:

Applicants would also like to bring the Examiner's attention to certain structural errors in the published version of this application. It is noted that the structural formulae for compounds 40a, 59, 60 and 63 in Paragraphs [0472], [0589], [0593] and [0604], respectively, are incorrect based on the application as filed. As can be seen from pages 71, 86, 87 and 88 of the application as filed, each of these compounds has an oxygen located between the aromatic ring and the carbonyl moiety to the left of the aromatic ring in each structure. Applicants respectfully request that these errors by the Office in the publication of the application be noted such that they do not reoccur in any patent which may ultimately issue from this application.

Conclusion:

Applicants respectfully submit that neither required election is necessary or warranted in this application. Simultaneous examination of Groups I, II, III, IV, V and all disclosed species, will present no undue burden on the Examiner. Accordingly, Applicants respectfully request that all pending claims 89-128 be examined on their merits.

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Respectfully submitted,

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[Signature]
By _____

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